



An Application of the Kipling Method to DNA Validation in the 21st Century

Questions to Consider

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Why am I validating a new system?

Faster Results

Cheaper Cost

Better Results

Usually – Pick 2 of the 3

Questions to Consider - Goals

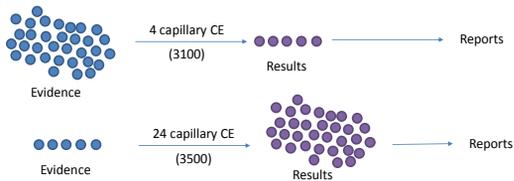
- I have asked many labs what happens when you get a qPCR result that equals 0 ng/uL ?
- Many answer – we do an STR test anyway.
- New STR kits are now more sensitive than the qPCR assays we use to quant.
- The next generation of qPCR kits show promise for better accuracy of zero results.

Cost-Benefit Analysis

- Determine the number of zero quants gave reportable results.
- Experiment with a new qPCR assay – is it better?
- How many fewer STR reactions could you save (including labor, CE supplies, etc...) by moving to the new qPCR assay?
- Does this justify the move to change your qPCR assay?

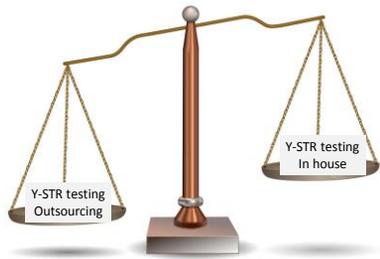
Questions to Consider - Goals

- Is greater sample throughput the goal?
- Will you simply move the bottleneck downstream?



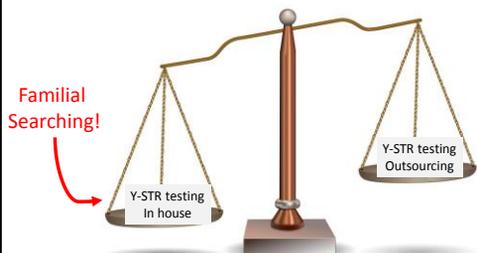
Questions to Consider - Gains

- Cost Analysis and/or Value added – **what** are you trying to gain?



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Questions to Consider – Evaluate Personnel

- Project Leader – planning and oversight
- The “hands” – good pipetting skills
- The “cruncher” – Excel skills/statistical analysis
- When, Where – do I look for help?
 - Stats professor at local university
 - MFS student for the summer?

What about outsourcing validation?

- Several companies (ThermoFisher, Sorenson, Bode) offer this service now.
- Advantages – They do it all! “economical” in the sense that they try not to perform unnecessary experiments.
- Disadvantages – must be able to understand their experiments/conclusions.

Questions to Consider – Evaluate Equipment

- Can you convince the vendor to give you a loaner instrument for evaluation before you invest multiple \$\$\$?
- Software – find out about computer requirements (memory, OS, etc...) before you buy. [My own personal example – NIST upgrades my computer to 64 bit encryption, one program I use frequently operates on 32 bit encryption.]

Questions to Consider – Supplies

- Can you convince the vendor to give you a test kit for evaluation?
- Some vendors will sell a 100 reaction kit at a reduced cost compared to the standard kit.
- Initial issues with RFID-tagged reagents created difficulties at many labs.

Questions to Consider – Training

- Who will take the lead on training the lab on the newly validated system?
- Small teams over time? All at once? Train the trainer?
- Prepare the lab with seminars/literature review (invite the vendor to host these).
- Resources!

Questions to Consider – Training

- Don't forget your customers!
- For example – moving to a probabilistic genotyping software system for mixture interpretation.
- Police, Lawyers and Judges – What's a LR? Admissibility hearings – will you be on your own?

Questions to Consider – Other Items

- QA/QC requirements
- Guidance documents – perhaps they don't exist at the moment (e.g. SWGDAM document on Validation of Probabilistic Software; Rapid DNA).
- Proficiency testing – How will this work for NGS? **Additional cost for the lab!**

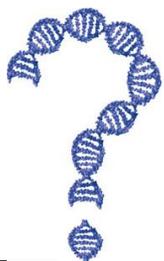
Questions to Consider – Reduced Casework

- During any validation – you will have some reduction in casework as you dedicate resources to this process.
- Goal – improved efficiencies and production. Factor this into your cost-benefit analysis.

Acknowledgments

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